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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/948,710	10/08/97	BROD	

IM21/1023

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EXAMINER	
GAYHEART, C	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 10/23/98

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/946710	BROD
Examiner	**Group Art Unit**
SAYALA	1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8/21/98.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Seq Error Report

Office Acti n Summary

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-4, 6 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines 12-26, col. 13, and the claims. Such disclosure meets the claims.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 5 is rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The disclosure is the same as above as discussed for claims 1

and 8. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

5. Claims 1-18 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view of Shibutani et al. (Iyakuhin Kenkyu, vol. 18(4), pp. 571-82, 1987) and further in view of Sobel (abstract of WO 9420122 or US Patent 5624895).

The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity

side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc. Note that although Cummins discloses interferon for autoimmune diseases which includes the diabetes claimed herein, the reference does not expressly state that the disease condition is diabetes. However Sobel shows the use interferon for diabetes. See col. 8, line 63 to col. 9, line 5 and claims 11-12 and 18.

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

7. Applicant's arguments filed 8/21/98 have been fully considered but they are not persuasive.

On page 3 of the response applicant has criticized the Cummins reference for showing only one anecdotal report. He argues that "the extremely limited clinical data" cannot be

considered enabling and therefore should be held "incredible". Enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation". *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 140, 1404 (Fed. Cir. 1988). The specification and data therein is considered to be adequate to provide the skilled worker enough to practice the invention without "undue experimentation". A patent cannot be called "non-enabling" because applicant has produced data from 27 patients and 18 controls versus one example in the patent used.

As for amounts, the claims rejected do not contain the limitation that applicant has based his arguments on (SEE page 6, lines 1-2 of the response).

Applicant's discussion of Cummins' mode of administration at page 6 of the response is also not persuasive. There is nothing clearly distinguishable between "orally administering...such that the ...interferon is ingested after oral administration" and Cummins' mode. Applicant has argued at pages 7 and 8 that in his specification the interferon was fed through a needle inserted into the stomach and there was no oral or pharyngeal contact. There are no such limitations in the claims, however, and the relevance of this in view of the instantly claimed limitations is not clear.

Applicant also argues that there was only "brief" exposure of interferon to the oral mucosa in his method. The claims herein do not recite anything to this end and

there is no recitation to show such a "brief" exposure only.

Applicant's pointing out col. 5, lines 50-55 of Cummins is also not understood. The patent clearly teaches "Daily dosage of interferon....as a single dosage". Nowhere in any statute is there a requirement that only the preferred embodiment of the reference should be considered a teaching and the rest of the reference be ignored.

Both the traversal of the rejection over claim 5 and the declaration have been carefully reviewed and considered and the above discussions apply here too.

Applicant's traversal of the rejection of claims 1-18 at pages 10-13 is in error. Test for combining references is not what individual references themselves suggest but what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1970). Applicant has improperly criticized the references individually where the rejection is based upon the combined teachings of the references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be established by attacking references taken individually when rejection is based on a combination of references. *Ex parte Campbell* 172 USPQ 91 (BPA&I 1971). Note that Sobel was used only to show that the use of interferon for treating diabetes was known in the art. And Shibutani's abstract is used to show toxicity studies only and the motivation it provides to the artisan.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP.. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Examiner C. Sayala at telephone number (703) 308-3035. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0166. The group fax number is (703) 305-3599.

C. Sayala
Primary Examiner
Group 1700.